SEP 2 1 2001

K012093

510(k) Summary

The following safety and effectiveness summary has been prepared pursuant to requirement for 510(k) summaries specified in 21CFR¶807.92(a).

807.92(a)(1)

Submitter Information

AETmed, S.p.A.
Viale Cembrano, 4C
16148 Genova, Italy
Phone: 39010307091
Facsimile: 390103070937

Contact Person: Massimiliano Peri

Date: April 30, 2001

807.92(a)(2)

Trade Name: AETmed Image Processing Software

Common Name: Image Processing Software

Classification Name(s): System, Image Processing

Classification Number: LLZ

807.92(a)(3)

Predicate Device(s)

Electromed	View NT	K000474
Applicare	Radworks Medical Imaging Software with Quality Control Module	K982862
Cemax-Icon	Accurad Image management System; AutoRad Regustr	K955092

Additional Substantial Equivalence Information is provided in the following substantial Equivalence Comparison Table.

510(k) Summary
AETmed Image Processing Software
AETmed, S.p.A.

807.92(a)(4)

Device Description

The AETmed Medical image processing Software is a software device intended to be used by qualified medical professionals, after proper installation on an appropriate hardware platform, for capturing, retrieving, viewing, processing, printing, archiving, and communicating medical images, such as cardiac catheterization, echocardiography, and general radiological studies.

The Version 3.0 DICOMed Family Software System consists of the following components:

- DICOMed DIG.IT - image acquisition and CD recording station
- DICOMed P@CS - image archiving manager
- DICOMed Review Cardio - review workstation for cardiology
- DICOMed Review - diagnostic review workstation for radiology

510(k) Summary
AETmed Image Processing Software
AETmed, S.p.A.

807.92(a)(5)

Intended Use(s)

The AETmed Medical image processing Software is a software device intended to be used by qualified medical professionals, after proper installation on an appropriate hardware platform, for capturing, retrieving, viewing, processing, printing, archiving, and communicating medical images, such as cardiac catheterization, echo-cardiography, and general radiological studies.

510(k) Summary
AETmed Image Processing Software
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Table 1 – Substantial Equivalence Comparison Chart

Feature				
Product	**AETmed Image Processing software (This submission)**	**VIEW NT™**	**Radworks Medical Imaging Software with Quality Control Module**	**Accurad Image Management System, AutoRad Regustr**
Manufacturer	AETmed	Electromed	Applicare	Cemax Icon
510(k) Number	---	K000474	K982862	K955092
Classification	892.2050; Class II	892.2050; Class II	892.2050; Class II	892.2050; Class II
Intended Use	The AETmed Medical image processing Software is a software device intended to be used by qualified medical professionals, after proper installation on an appropriate hardware platform, for capturing, retrieving, viewing, processing, printing, archiving, and communicating medical images, such as cardiac catheterisation, echo-cardiography, and general radiological studies.	VIEW NT is a powerful real-time cardiac image acquisition, display, processing and communication system enhancing the performance of a Cathlab and its connection to the Digital Image Archiving network. Both Quantitative Coronary Analysis and Ventricular Analysis Software's are included with the VIEW NT.	The RadWorks Medical Imaging Software, from Applicare Medical Imaging, B.V., when installed on an appropriate hardware platform, is intended to provide capability for the acceptance, display, storage, and digital processing of medical images. Options allow for additional capability, including transmission of images over local area networks or public communications channels, digitization of film images, acceptance of digital images directly from different medical image modalities, and quality control review and revision of studies.	Cemax Icon provides PACS, computed radiography and teleradiology software. The software is scalable and addresses all aspects of medical image acquisition, viewing, storage and printing.
Graphical User Interface	Yes	Yes	Yes	Yes
Platform	PC	PC	PC	Workstation
Operating System	Windows NT, Windows 2000	Windows NT	Windows NT	UNIX
Display Resolution	Up to 2048x2560	1024x768	Up to 2048x2560	Up to 2048x2560

Feature				
Product	**AETmed Image Processing software (This submission)**	**VIEW NT™**	**Radworks Medical Imaging Software with Quality Control Module**	**Accurad Image Management System, AutoRad Regustr**
Gray scale resolution	From 8 bits, 256 levels to 24 bits true color	8 bits, 256 levels	From 8 bits, 256 levels to 24 bits true color	From 8 bits, 256 levels to 24 bits true color
Multi-monitor support	Yes	Yes	Yes	Yes
Patient Demographics	Yes	Yes	Yes	Yes
Networking	TCP/IP	TCP/IP	TCP/IP	TCP/IP
Image Communication	DICOM Compliant	DICOM Compliant	DICOM Compliant	DICOM Compliant
DICOM Compliant	Yes	Yes	Yes	Yes
Image Compression	JPEG loss-less	JPEG loss-less, JPEG lossy	JPEG loss-less, JPEG lossy	JPEG loss-less, JPEG lossy
Video signals grabbing	Yes	Yes	Yes	Unknown
Analogic Video Input format	525, 625, 1023, 1049, 1249; interlaced or progressive	525, 625, 1023, 1049, 1249; interlaced or progressive	525, 625; interlaced or progressive	N/A
Analogic Video Input rate	<= 30 fps	<= 30 fps	< 30 fps	N/A
Image Archiving (Hard Disk)	Yes	Yes	Yes	Yes
Image Archiving (Removable media)	CD-R, MOD, DVD, DLT, other DICOM Entities	CD-R, other DICOM Entities	CD-R, MOD, DVD, DLT, other DICOM Entities	CD-R, MOD, DVD, DLT, other DICOM Entities
Image Review	Still images, cine-loops, Window, level, zoom, magnifying lens, Configurable layout	Still images, cine-loops, Window, level, zoom, magnifying lens	Still images, cine-loops, Window, level, zoom, magnifying lens, Configurable layout	Still images, cine-loops, Window, level, zoom, magnifying lens, Configurable layout
Image Processing	Annotations, Distances, Angles, Pixel Values, Pixel Distribution, Grey level statistics, Quantitative Coronary Analysis, Left Ventricle Analysis	Annotations, Distances, Angles, Pixel Values, Pixel Distribution, Grey level statistics, Quantitative Coronary Analysis, Left Ventricle Analysis	Annotations, Distances, Angles, Pixel Values, Pixel Distribution, Grey level statistics	Annotations, Distances, Angles, Pixel Values, Pixel Distribution, Grey level statistics
3D Image Processing	MPR, MIP, mip, Volume rendering	No	MPR, MIP, mip, Volume rendering	Unknown
Quality Control	Yes	Unknown	Yes	Yes
Workflow management	Yes	Unknown	Yes	Yes
Image Database	Yes	Yes	Yes	Yes

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 21 2001

AETmed S.P.A.
% Ms. Colleen Hittle
Partner
The Anson Group, LLC
7992 Castleway Drive
INDIANAPOLIS IN 46250

Re: K012093
Trade/Device Name: AETmed Image Processing Software PACS
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture Archiving and Communications Sy
Regulatory Class: II
Product Code: 90 LLZ
Dated: July 3, 2001
Received: July 5, 2001

Dear Ms. Hittle:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

Applicant: AETmed, S.p.A.

510(k) Number (if known): K012093

Device Name: AETmed Medical image processing software

Indications For Use:

The AETmed Medical image processing Software is a software device intended to be used by qualified medical professionals, after proper installation on an appropriate hardware platform, for capturing, retrieving, viewing, processing, printing, archiving, and communicating medical images, such as cardiac catheterization, echo-cardiography, and general radiological studies.

(PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ **OR** Over The Counter _____

(Per 21 CFR, 801.109)

(Optional Format 1-2-96)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K012093